An Agricultural Law Research Article

Is a Picture Worth More Than 1,000 Words? The Fourth Amendment and the FDA's Authority to Take Photographs Under the Federal Food, Drug, and Cosmetic Act

by

Neal D. Fortin

June 2006

Originally published in the Journal of Food Law & Policy
2 J. FOOD L. & POL'Y 239 (2006)

A National AgLaw Center Research Publication

Is a Picture Worth More Than 1,000 Words? The Fourth Amendment and the FDA's Authority to Take Photographs Under the Federal Food, Drug, and Cosmetic Act

Neal D. Fortin
Attorney at Law
Okemos, Michigan

I. INTRODUCTION

Food and drug law scholarship, once upon a time a charming specialty field, has developed into a substantial legal arena.[1] In the past, food and drug law was rich like fine pastries from a Parisian patisserie, but too refined and specialized to have much of an impact on the legal scholar's diet. Today, no longer just a boutique interest, the field encompasses important foundational issues in constitutional and administrative law and involves noteworthy issues in other areas of law, such as products liability.[2] This broadened field attracts scholarship from practicing lawyers and agency officials, as well as, law professors.[3]

From a human-interest perspective, the range of products regulated by the Food and Drug Administration (FDA) touches the lives of nearly every American every day.[4] Yearly, FDA regulates over $1 trillion worth of products, which account for twenty-five cents of every dollar spent by American consumers.[5] Moreover, the FDA's activities and initiatives often warrant headline news.[6]

---

1. *See*, *e.g.*, Peter Barton Hutt, *The Transformation of United States Food and Drug Law*, 60 J. ASS'N FOOD & DRUG OFFICIALS 9 (1996).

2. *Id.*

3. Lars Noah, *One Decade of Food and Drug Law Scholarship: A Selected Bibliography*, 55 FOOD & DRUG L.J. 641 (2000).

4. FDA, THE FOOD AND DRUG ADMINISTRATION: AN OVERVIEW (Jan. 11, 1999) (ensuring that our food is safe and wholesome, that medicines and medical devices are safe and effective, and that cosmetics are not harmful)., *available at* http://www.cfsan.fda.gov/fdaoview.html.

5. *Id.*

For these reasons, the FDA's regulatory authority provides a rich arena for legal commentary. Therefore, it is surprising that so little has been written on the FDA's authority to take photographs under the Federal Food, Drug, and Cosmetic Act (FDCA),[7] particularly since this is an area of long, ongoing controversy in the food and drug field.[8] Two currents roil beneath the surface of this issue—our Fourth Amendment right against unreasonable searches and the scope of the FDA authority to inspect under FDCA. Yet, a recent literature search revealed a solitary law review article.[9]

To fill the gap, this article analyzes the FDA's authority to take photographs during regulatory inspections. It begins with a review of the FDA's statutory authority to conduct establishment inspect-tions, and then discusses the FDA's administrative policy and the case law on the scope of the FDA's authority to take photographs during administrative inspections. Most discussions of the scope of the FDA's authority to take photographs conclude that FDCA and case law do not expressly or clearly answer the question.[10]

This article argues that the lack of express authority to take photographs does not equate with the lack of legal clarity. Applying Fourth Amendment scholarship and the tools of statutory construction to the issue reveals that the FDA's authority to take photographs is generally co-extensive with the agency's authority to conduct regulatory inspections. Notwithstanding the legal intelligibility, clarification of the statutory language would increase government efficiency and reduce the friction between FDA and regulated businesses.

II. THE FDA'S INSPECTIONAL AUTHORITY

A. Overview of the FDA's Inspectional Authority

Section 704 of FDCA[11] empowers FDA to enter and inspect any establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into

---

6. *See* http://www.fda.gov.

7. Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified at U.S.C. §§ 301-397) (2000).

8. *See*, *e.g.*, Frederick H. Branding & James M. Ellis, *Underdeveloped: FDA's Authority to Take Photographs During an FDA Establishment Inspection Under Section 704*, 58 FOOD & DRUG L.J. 9 (2003).

9. *Id.*

10. *See*, *e.g.*, *id.* at 9 & 16.

11. 21 U.S.C. § 374 (Supp. 2005).

interstate commerce or after such introduction.[12] FDCA specifies that this inspection authority covers all pertinent equipment, finished and unfinished materials, containers, and labeling.[13] However, the Act is silent on photography during inspections.

In addition, Section 704 provides that, with certain limitations, the inspection authority extends to all food records and other related information when FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious, adverse health consequences or death to humans or animals.[14] When the inspection pertains to prescription drugs, nonprescription drugs intended for human use, or restricted medical devices, the FDA's inspection authority is broader yet and extends to "all things therein (including records, files, papers, processes, controls, and facilities)."[15]

---

12. 21 U.S.C. § 374(a)(1) (Supp. 2005) reads in pertinent part:
    (a)(1) For purposes of enforcement of this chapter, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized
    (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and
    (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein . . . .

13. *Id.*

14. 21 U.S.C. § 374(a)(1)(B) (Supp. 2005).

15. 21 U.S.C. § 374(a)(1)(B) (Supp. 2005) reads in pertinent part:
    In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter.

B. The FDA's Position on Its Authority to Photograph

The FDA policy on photography during establishment inspecttions[16] is published in the agency's Investigations Operations Manual (IOM).[17] IOM, Chapter 5, subchapter 523, "Photographs – Photocopies," discusses the taking of photographs during inspections.[18] IOM cites examples of conditions or practices that may be "effectively documented by photographs," such as evidence of rodent or insect infestation, contamination of raw materials or finished products, and employee practices contributing to contamination or to violative conditions.[19] IOM states, "[s]ince photographs are one of the most effective and useful forms of evidence, every one should be taken with a purpose. Photographs should be related to insanitary conditions contributing or likely to contribute filth to the finished product, or to practices likely to render it injurious or otherwise violative."[20]

FDA directs its inspectors:[21]

> Do not request permission from management to take photographs during an inspection. Take your camera into the firm and use it as necessary just as you use other inspectional equipment.
> If management objects to taking photographs, explain that photos are an integral part of an inspection and present an accurate picture of plant conditions. Advise management the

---

16. FDA also provides policy guidance with its COMPLIANCE POLICY GUIDES, COMPLIANCE PROGRAM GUIDANCE MANUAL, and its REGULATORY PROCEDURES MANUAL, *available at* http://www.fda.gov/ora/compliance_ref/cpg/default.htm; http://www.fda.gov/ora/cpgm/default.htm; and http://www.fda.gov/ora/compliance_ref/rpm/default .htm.

17. OFFICE OF REGULATORY AFFAIRS, FDA, Investigations Operations Manual (IOM) 2005, *available at* http://www.fda.gov/ora/inspect_ref/iom/ [hereinafter IOM].

18. *Id.* at Chapter 5, subchapter 523.

19. *Id.*

20. *Id.*

21. "Inspector" and "field investigator" are terms often used interchangeably for field agents of FDA. While both are general terms and can apply to a variety of activities, the term inspector is used throughout this article to distinguish inspections (where a Form FDA 482, Notice of Inspection, is issued) from various investigations, particularly criminal investigations. In 1992-93, FDA added armed criminal investigators, and the FDA's criminal investigations raise other constitutional issues, such as *Miranda* warnings, which are not required during administrative inspections. *See*, *e.g.*, United States v. Gel Spice Co., Inc., 773 F.2d 427 (2d Cir. 1985).

> United States [c]ourts have held that photographs may lawfully be taken as part of an inspection.[22]

The FDA's operational policy not to request permission to take photographs often raises the ire at regulated firms for its seeming rudeness. The rationality of the FDA's policy, however, must be determined with the context of the FDA's Section 704 inspection authority and relevant case law.

C. The Scope of Section 704 Inspection Authority

The scope of the FDA's authority for inspections under Section 704 is general with few specific constraints. The most specific constraint is a limit on the FDA's access to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting requirements).[23]

FDCA also sets a few procedural requirements. Before entering an establishment or inspecting, the FDA inspector must present appropriate credentials and a written notice to the owner, operator, or agent in charge.[24] The FDA inspector may inform a firm of the purpose of the inspection (e.g., routine, complaint investigation, pre-approval, etc.). However, the FDA's Notice of Inspection form[25] does not specifically supply the reason for the inspection.[26] In addition, the notice of inspection is not required to include the reasons for the inspection or what the inspector expects to find.[27]

The major constraint on FDA is a rule of reasonableness. Inspections must be "at reasonable times and within reasonable limits and in a reasonable manner."[28] The reasonableness of the time,

---

22. IOM, *supra* note 17, at 523.01.

23. 21 U.S.C. § 374(a)(1) (Supp. 2005).

24. 21 U.S.C. § 374(a)(1) (Supp. 2005).

25. FDA, Notice of Inspection Form FDA-482, *available at* http://www.fda.gov/ora/inspect_ref/iom/exhibits/x510a.html.

26. *Id.*

27. Daley v. Weinberger, 400 F. Supp. 1288 (E.D.N.Y. 1975), *aff'd*. 536 F.2d 519 (2d Cir. 1976) and *cert. denied* 430 U.S. 930 (1977); *see also* United States v. Jamieson-McKames Pharm., Inc., 651 F. 2d at 538 (8th Cir. 1981) ("The notice of inspection used in this case satisfies at least some of these criteria. It informs the 'owner or agent in charge' of the 'scope and objects of the search.' [footnotes omitted]").

28. 21 U.S.C. § 374(a)(1)(B) (Supp. 2005).

limits, and manner of inspections has only occasionally been litigated; but when an inspection's reasonableness has been challenged, courts largely determine reasonableness based on whether FDA met the procedural requirements of Section 704.[29] Reasonableness will also be determined from the facts of each situation, such as the enforcement needs under the statute and whether an unnecessary burden is placed on a firm.[30]

D. Refusal to Permit Inspection

Refusal to permit an FDA inspector to duly[31] enter and inspect a regulated facility is a violation of section 301(f) of FDCA.[32] FDA considers a section 301(f) refusal to be a refusal to permit an inspection or prohibiting an inspector from obtaining information to which FDA is entitled by law.[33] A refusal may be a partial refusal, for example, a refusal to permit access to some records or some parts of a facility to which FDA is authorized to inspect.

Whether a refusal to allow photographs is a refusal (or partial refusal) of inspection under Section 301(f) remains an issue of debate.[34] In the absence of explicit language in the statute, it has been contended that refusal to permit photography should not be considered a Section 301(f) refusal of inspection.[35]

---

29. *See*, *e.g.*, *Gel Spice*, 601 F. Supp. at 1228 (holding that photographing was not unreasonable where "the agents were in the warehouse pursuant to lawful authority and followed all procedural requirements mandated under 21 U.S.C. § 374").

30. *See*, *e.g.*, *Jamieson-McKames*, 651 F.2d at 537 (noting that the reasonableness of the warrantless search is dependent on the "specific enforcement needs and privacy guarantees of each statute").

31. The inspector presents proper identification and a valid inspection notice during a reasonable time as required by FDCA Section 704, 21 U.S.C. § 374 (2000).

32. 21 U.S.C. § 331(f) (Supp. 2005) (stating that "[t]he refusal to permit entry or inspection as authorized by section 374 of this title is a prohibited act").

33. IOM, *supra* note 17, at § 514.

34. Branding & Ellis, *Underdeveloped*, *supra* note 8 at 12:

> Whether a refusal to allow photographs is an actual refusal of the inspection under section 704 is not settled. . . . An investigator may characterize a firm's nonconsent to the taking of photographs as a refusal of the inspection or of information. In the absence of explicit legal authority in the statute, however, such nonconsent should not, as a matter of legal interpretation, be referred to as a refusal of the inspection.

35. *Id*.

As a matter of legal interpretation, if photography is a reasonable part of a Section 704 inspection, then refusal to permit photography would be a Section 301(f) violation, "The refusal to permit entry or inspection as authorized by Section 374 (i.e., 704) of this title."[36] Nonetheless, it remains arguable that a court would not find a 301(f) violation, a refusal to permit inspection, when a firm courteously refused to consent to photography, but otherwise allowed the inspection. Particularly when the immediate issue will have been resolved by a search warrant, a court may be reluctant to mete out punishment.

The controversy is unlikely to be resolved by the courts because the circumstances foreclose the two basic occasions for litigation. The first occasion is the pursuit of a complaint for refusal to permit photography. The second is the FDA's use of search warrants, which preclude the need for other judicial action.

FDA has not yet pursued a complaint for the refusal to permit photography and is unlikely to do so in the future.[37] In part, this is because the issue is arguable, but the likely reason for such reluctance is arguably due to pragmatism in marshalling limited resources. The FDA's powers and responsibilities have never been matched with enough resources to enforce all issues within its oversight. Therefore, the agency must decline to take action against some violations, and the FDA's authority to do so has been upheld in court actions.[38] In addition, enforcement discretion is not the exclusive choice of FDA. The United States Department of Justice (DOJ) and the United States Attorney for the judicial district in which FDA seeks judicial remedy also share discretion in filing court actions. Court actions are resource-intensive for both FDA and DOJ, and the agencies perform several layers of review before a case can proceed. All of these factors combine to make the FDA's pursuit of a complaint for failure to permit photography unlikely.

The lack of a case on point also exists because, if a firm refuses to permit photography, and FDA determines photography is necessary, FDA will seek an administrative search warrant.[39] The FDA's boilerplate language for administrative search warrants includes authorization of photography. Once the search warrant is issued, refusal to permit inspection photography in the face of search warrant

---

36. 21 U.S.C. § 331(f) (Supp. 2005).

37. FDA has never prosecuted a firm for failure to permit photography. E-mail from Evelyn DeNike, Consumer Affairs Officer, FDA (Aug. 29, 2005) (on file with the author).

38. *See*, *e.g.*, National Milk Producers Fed'n v. Harris, 653 F.2d 339 (8th Cir. 1981) (holding that FDA's enforcement proceedings were discretionary); Heckler v. Chaney, 470 U.S. 821 (1985) (holding that FDA's decisions not to take certain enforcement actions are not subject to judicial review under the APA).

39. IOM, *supra* note 17, at § 523.01 ("If management refuses, advise your superior so legal remedies may be sought to allow you to take photographs, if appropriate.").

authority mutes the issue of authority under FDCA. After an FDA inspector obtains a search warrant, federal marshals will execute it. At that point, refusal to permit inspection can result in arrest by the federal marshals. Refusal in the face of a search warrant is punishable by judicial contempt of court sanctions[40] in addition to separate criminal violations under FDCA.[41] Additionally, refusal to permit inspection in such circumstances might result in seizures and injunctive actions.

Photographic evidence can be very damaging.[42] Because the issue of the legality of a firm refusing to permit photography absent a warrant is unlikely to be settled by the courts, and because the risk of prosecution is remote, many firms are likely to continue to refuse to consent to photography.[43] Thus, the status quo is likely to continue where some firms refuse consent, and FDA seeks an administrative warrant when the agency considers photography necessary to complete their inspection.

In summary, FDCA provides FDA with the power to enter and inspect regulated establishments. The statute applies a general rule of reasonableness. The FDA's policy is not to request permission to photograph during inspections, but to proceed taking photographs unless stopped. Refusal to permit an FDA inspector to enter and inspect is a violation of FDCA, but it is unclear whether a firm would be prosecuted for refusing permission to take photographs absent a warrant.

The next section analyzes the applicability of Fourth Amendment protections to the FDA inspections and inspection photography in particular. The main issues are whether Section 704 inspections require search warrants, and when search warrants are required in the absence of consent to inspection, including the absence of consent to photography. The subsequent section

---

40. *See*, *e.g.*, Becton, Dickinson & Co. v. FDA, 448 F. Supp. 776, 780 n.6 (N.D.N.Y. 1978) *aff'd*. 589 F.2d. 1175 (2d Cir. 1978) ("This [c]ourt cannot, however, condone the actions of the defendants in refusing to abide by a Writ lawfully issued by this [c]ourt. . . . This cuts against all notions of law and order, and sets the stage for an obviously intolerable confrontation in every case in which a search warrant is issued.").

41. 21 U.S.C. § 331(e) and (f) (Supp. 2005), amended by Pub. L. 109-59, Tit. VII, § 7202 (d), (e), 119 Stat 1913 (2005) (amended Aug. 10, 2005).

42. *See* IOM, *supra* note 17, at §.523 ("Since photographs are one of the most effective and useful forms of evidence, every one should be taken with a purpose. Photographs should be related to insanitary conditions contributing or likely to contribute filth to the finished product, or to practices likely to render it injurious or otherwise violative.").

43. Firms should be aware that there might be repercussions for refusing to permit photography beyond FDA returning with a search warrant. For example, such an action may make the inspector suspicious, more vigilant, and increase the frequency and duration of inspections. Inspectors may increase scrutiny when the actions or attitude of a firm appear suspicious. In addition, the inspectors always retain a degree of discretion. An uncooperative attitude on the part of firm management may well result in an uncooperative attitude by the inspector.

analyzes the statutory construction of FDCA to determine whether it supports the FDA's authority to take photographs during regulatory inspections. The relevant case law is also examined for further insight into the FDA's authority to take photographs.

III. FOURTH AMENDMENT CONSTRAINTS

Government-Inspections are a form of search and thus are constrained by the Fourth Amendment.[44] Except in carefully defined circumstances, the Fourth Amendment requires government agents to obtain a search warrant before inspecting private premises.[45]

Inspections under FDCA are within one of those exceptions. FDA is not required to obtain a search warrant to inspect an establishment regulated under Section 704, so long as the inspection is conducted reasonably as to time, place, and method.[46] An individual search warrant is not necessary because FDCA serves as a substitute for a search warrant.[47]

Such warrantless inspections have been held to be fully consistent with the Fourth Amendment.[48] The Supreme Court has upheld warrantless inspections for industries "long subject to close super-

---

44. The Fourth Amendment provides:

> The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.

U.S. CONST. amend. IV.

45. Under the Fourth Amendment, "except in certain carefully defined classes of cases, a search of private property without proper consent is 'unreasonable' unless it has been authorized by a valid search warrant," Camara v. Municipal Ct., 387 U.S. 523, 528-29 (1967). *See also* See v. City of Seattle, 387 U.S. 541, 543 (1967):

> The businessman, like the occupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property. The businessman, too, has that right placed in jeopardy if the decision to enter and inspect for violation of regulatory laws can be made and enforced by the inspector in the field without official authority evidenced by warrant.

46. United States v. New England Grocers Supply Co., 488 F. Supp. 230, 238-39 (D. Mass. 1980); *see also* United States v. Business Builders, Inc., 354 F. Supp. 141, 143 (N.D. Okla. 1973); United States v. Del Campo Baking Mfg. Co., 345 F. Supp. 1371, 1376-77 (D. Del. 1972).

47. *Id.*

48. *See*, *e.g.*, *New England Grocers Supply Co.*, 488 F. Supp. at 238.

vision and inspection"[49] and for "pervasively regulated business[es]."[50] This search warrant exception is often called the *Colonnade-Biswell* exception, so named for the paired rulings that delineate the exception.[51]

Under the *Colonnade-Biswell* exception, the government may conduct a search of a "closely regulated" commercial business without a warrant if three criteria are met.[52] First, the regulatory inspecttion scheme must be supported by a "substantial" government interest.[53] Second, warrantless inspections must be "necessary to further [the] regulatory scheme."[54] Third, "the statute's inspection program, in terms of the certainty and regularity of its application, [must] provid[e] a constitutionally adequate substitute for a warrant."[55] In other words, the statute must be "sufficiently comprehensive and defined that the owner of commercial property cannot help but be aware that his property will be subject to periodic inspections undertaken for specific purposes," and the inspection program must be "carefully limited in time, place and scope." [56]

A. Application of the Colonnade-Biswell Exception to Photography

Numerous court decisions support the application of the *Colonnade-Biswell* exception to inspections authorized under FDCA.[57] Businesses regulated under FDCA and subject to Section 704

---

49. Colonnade Catering Corp. v. United States, 397 U.S. 72, 77 (1970) (addressing the Bureau of Alcohol, Tobacco, and Firearms' inspectional authority over liquor).

50. United States v. Biswell, 406 U.S. 311, 316 (1972) (regarding a warrantless inspection of a pawnshop, which was federally licensed to sell guns pursuant to the Gun Control Act of 1968). A system of warrantless inspections was deemed necessary "if the law is to be properly enforced and inspection made effective." *Id*.

51. *See*, *e.g.*, Donovan v. Dewey, 452 U.S. 594, 602 (1981).

52. New York v. Burger, 482 U.S. 691, 702 (1987).

53. *Id.*

54. *Id.*

55. *Id.* at 703.

56. *Id.*

57. *See generally* Daniel H. White, Annotation, *Validity of Inspection Conducted under Provisions of Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 374(9)) Authorizing FDA Inspectors to Enter and Inspect Food, Drug, or Cosmetic Factory, Warehouse, or Other Establishment*, 18 A.L.R. Fed. 734 (2004); *see also Jamieson-McKames Pharm.*, 651 F.2d 532 (regarding a drug manufacturing industry); *New England Grocers Supply Co.*, 488 F. Supp. 230 (involving a food-supply warehouse); United States v. Acri Wholesale Grocery Co., 409 F.

inspections would have a difficult battle convincing a court that *Colonnade-Biswell* does not apply. As the court noted in *United States v. Business Builders, Inc*.:[58]

> It would be an affront to common sense to say that the public interest is not as deeply involved in the regulation of the food industry as it is in the liquor and firearms industries.[59] One need only to call to mind recent cases of deaths occurring from botulism. Modern commerce has devised such an efficient and rapid means of distribution of food products to the consumer that a batch of contaminated food may cause widespread illness and death before the public can be warned and the contaminated products removed from the market.[60]

The *Colonnade-Biswell* exception to the Fourth Amendment's warrant requirement is considered constitutionally acceptable largely because businesses that are subject to comprehensive, government regulatory supervision have a "reduced expectation of privacy."[61] The Supreme Court discussed this reduced expectation in *New York v. Burger*: This expectation is particularly attenuated in commercial property employed in "closely regulated" industries. The Court observed in *Marshall v. Barlow's, Inc*.: "Certain industries have such a history of government oversight that no reasonable expectation of privacy, could exist for a proprietor over the stock of such an enterprise." [citations omitted][62]

The *Colonnade-Biswell* exception permits warrantless inspections of a closely-supervised and pervasively-regulated industry because "when an entrepreneur embarks on such a business, he has chosen to subject himself to a full arsenal of governmental regulation,"[63] and "in effect consents to the

---

Supp. 529 (S.D. Iowa 1976) (food); *United States v. Business Builders, Inc.*, 354 F. Supp. 141 (N.D. Okla. 1973) (food); and *United States v. Del Campo Baking Mfg. Co.*, 345 F. Supp. 1371 (D. Del. 1972) (food).

58. *Business Builders*, 354 F. Supp. at 143.

59. Presumably, federal interest in liquor is pecuniary, due to the great amount of taxes collected from that industry. Likewise, federal interests in firearms is the prevention of violent crime. However, it would seem to this Court that the public health and welfare under any system of values would be more important than revenue and suppression of criminal activity. *Id.* at n.1.

60. *Id.* at 143.

61. *New York v. Burger*, 482 U.S. 691, 702 (1987).

62. *Id.* at 700.

63. Marshall v. Barlow's, Inc., 436 U.S. 307, 313 (1978).

restrictions placed on him."[64] In light of such a history of government scrutiny, such a business has no "reasonable expectation of privacy."[65]

Applying this reduced expectation of privacy to the FDCA inspections begs the rhetorical question: Is there any expectation of privacy from photography in areas where FDA has the authority to inspect? Common sense dictates that where FDA has the statutory authority to inspect—to observe, document, and sample—there is no Fourth Amendment expectation of privacy.[66] Thus, there would be no Fourth Amendment protection against FDA photographing areas where FDCA authorizes FDA to inspect.[67]

Under Fourth Amendment jurisprudence, the test is whether "the government's intrusion infringes on the personal and societal values protected by the Fourth Amendment."[68] Thus, photography by the FDA inspectors during a duly authorized inspection would violate the Fourth Amendment only if the business manifested a subjective expectation of privacy of the area photographed that society accepts as objectively reasonable.[69]

However, businesses regulated by FDA are well aware that during inspections the FDA inspectors will view and document observations in the establishment and take samples. Accordingly, an FDA-regulated firm (a business subjected to close supervision and pervasive regulation) would have no reasonable expectation of privacy in the areas under an inspection.[70] Moreover, the photography would be merely cumulative or duplicative of the inspector testimony, reports, and samples, which mitigates the intrusiveness of an inspection.[71] In the face of such government scrutiny, a

---

64. *Id*. (citing Almeida-Sanchez v. United States, 413 U.S. 266, 271 (1973)).

65. *Id*.

66. While photography may be deemed more intrusive into privacy that mere visual observation in some circumstances, it seems unlikely that this would be the case in the context of a regulatory inspection where the statute gives the authority to inspect, document conditions, and sample.

67. Again, attorneys must be careful when speaking with their clients. The author's experience is that some clients easily believe they have an inherent or constitutional right not be photographed.

68. Oliver v. United States, 466 U.S. 170, 171 (1984).

69. For application of this standard, *see* California v. Greenwood, 486 U.S. 35 (1988) (finding no reasonable expectation of privacy in garbage bags left at the curb).

70. *See Marshall*, 436 U.S. at 313.

71. *See*, *e.g.*, *Acri Wholesale Grocery Co.*, 409 F. Supp. 529 (finding that there was no unlawful or unwarranted intrusion by photography). The court noted, "Moreover, in this case the photographs introduced

business has no reasonable expectation of privacy against photography. Accordingly, the Fourth Amendment would not protect against photography of areas and items legitimately subject to FDA inspection. Nonetheless, the Fourth Amendment provides other protections, such as restraint against breaking and entering without a warrant.[72]

B. No Authorization for Forced Entry Without a Warrant

If a business denies FDA entry to inspect, no language in FDCA authorizes FDA to force entry or inspection. Absent express statutory authority to force entry or inspection without a warrant, the Fourth Amendment prevents authorization by implication.[73] The Supreme Court in *Colonnade Catering* sets out the reasoning behind this protection:

> Where Congress has authorized inspection but made no rules governing the procedure that inspectors must follow, the Fourth Amendment and its various restrictive rules apply. . . . [T]his Nation's traditions . . . are strongly opposed to using force without definite authority to break down doors. . . . Congress has broad authority to fashion standards of reasonableness for searches and seizures. Under the existing statutes, Congress selected a standard that does not include forcible entries without a warrant. It resolved the issue, not by authorizing forcible, warrantless entries, but by making it an offense for a licensee to refuse admission to the inspector.[74]

While *Colonnade* involved the federal liquor law, the provisions in FDCA are similar to those addressed in *Colonnade*.[75] Congress provided no authority in FDCA for FDA to force entries without a warrant, but Congress did make it an offense to refuse permission to enter or inspect.[76] This issue, at least with respect to FDCA, was addressed in *United States v. Jamieson-McKames Pharmaceuticals, Inc.*[77] The court found that the *Colonnade-Biswell* exception applied to inspections

---

into evidence at trial were merely cumulative of the inspectors' testimony regarding the insanitary conditions in the warehouse." *Id.* at 533.

72. *See*, *e.g.*, King v. City of Ft. Wayne, Ind., 590 F. Supp. 414, 428 (N.D. Ind. 1984).

73. *See Colonnade Catering Corp.*, 397 U.S. at 77 ("[T]his Nation's traditions that are strongly opposed to using force without definite authority to break down doors.").

74. *Id.* at 77.

75. *See*, *e.g.*, *Jamieson-McKames*, 651 F.2d at 539.

76. 21 U.S.C. § 331(f) (Supp. 2005) (stating that it is a prohibited act to refuse "to permit entry or inspection as authorized by section 374 of this title").

77. *Jamieson-McKames*, 651 F.2d 532.

under FDCA, but that the Act did not authorize FDA to force entry or inspection where consent was withheld.[78] The court found that if consent were withheld, a separate violation of FDCA would occur; but the FDA inspectors are required to obtain a warrant before the inspection can proceed.[79]

Although the *Jamieson-McKames* court stated, "that an inspection pursuant to a [Section] 374 [i.e., 704] notice to inspect is authorized only when there is a valid consent," this ruling followed the *Colonnade* decision.[80] In *Colonnade*, the Court found that, in the absence of statutory authorization by Congress to force entry, the Fourth Amendment restricted the government from *forcible* entry for inspection.[81]

Thus, out of context, the statement that a Section 704 inspection "is only authorized where there is valid consent," would be misleading.[82] More precisely, consent is not necessary for a valid FDA inspection under FDCA, but FDCA does not authorize FDA, absent consent, to force an entry or inspection without a warrant.[83]

This precision is important because the circumstances of a valid inspection without consent exist where a firm gave consent but the consent was invalid—for example, where consent to inspection

---

78. *Id.* at 539-40 ("It follows, therefore, as in *Colonnade*, that an inspection pursuant to a [Section] 374 notice to inspect is authorized only when there is a valid consent. If consent is withheld, a separate violation of the Act occurs, and the FDA inspectors are required to obtain a warrant before the inspection can proceed.").

79. *Id*. Other cases that hold that a search warrant is required in the absence of consent include United States v. Roux Lab., Inc., 456 F. Supp. 973 (M.D. Fla. 1978) and United States v. Litvin, 353 F. Supp. 1333 (D.D.C. 1973).

80. *Jamieson-McKames*, 651 F.2d at 539-40.

81. *Colonnade,* 397 U.S. at 77:

> Congress has broad authority to fashion standards of reasonableness for searches and seizures. Under the existing statutes, Congress selected a standard that does not include forcible entries without a warrant. It resolved the issue, not by authorizing forcible, warrantless entries, but by making it an offense for a licensee to refuse admission to the inspector.

82. For example, under *Colonnade*, 397 U.S. at 77, clients may well hear that consent to inspection is required for a valid inspection and fail to hear that it is a violation of the FDCA to deny consent to FDA for an authorized inspection. This has been the author's experience in practice. Some need to be told bluntly, "FDA can't break down your door if you don't let them in, but FDA has the authority to inspect, and refusing their entry to inspect violates the law."

83. *Business Builders*, 354 F. Supp. at 143 ("In effect, the statute takes the place of a valid search warrant. Thus, consent is immaterial and Defendants do not contend that the inspection was conducted unreasonably as to time, place or method.").

was involuntary because consent was only given under threat[84] of prosecution.[85] Hypothetically, invalid consent might also occur where a firm's employee lacks the authority to grant consent to FDA, but nonetheless permitted entry. Foremost, the Fourth Amendment restriction on forcible entry would not extend protection to situations where there was no force used but where was consent was vague or ambiguous. Consent in such situations is moot because the regulated firms are required to comply with a warrantless regulatory inspection.[86]

This matter relates to the reason why the issue of the FDA's authority to take photographs remains largely unexplored by the courts. When a firm refuses to permit FDA to take photographs during an inspection, FDA lacks the authority to take photographs forcibly.[87] Therefore, faced with a refusal to permit photography, FDA must obtain an administrative search warrant if they consider photographs necessary for their inspection.[88] Thus, the issue of the FDA's authority to take photographs never comes to a head. Once a search warrant is obtained, the issue of the reasonableness of photography under FDCA becomes moot.[89]

Therein rests the heart of the issue: Whether, absent the specific mention of photography in Section 704, FDA is nevertheless empowered to take photographs. As discussed above, an FDA-regulated industry would have no reasonable expectation of privacy against photography in the areas and items under inspection.[90] Therefore, the legitimate areas and items of the FDA inspection would

---

84. A person who believes that their consent is required for an FDA inspection will naturally construe FDA's explanation of the penalties for failure to permit inspection as a threat.

85. *See*, *e.g.*, *Business Builders*, 354 F. Supp. 142 (explaining defendants who argued there was no valid consent when they allowed inspection because they were threatened with criminal prosecution if they refused to permit an inspection). "[I]t is this [c]ourt's conclusion that in the circumstances of this case, neither consent nor a search warrant is necessary." *Id*
.

86. *See* United States v. Articles of Drug, 568 F. Supp. 1182, 1185 (N.D. Cal. 1983) ("To the extent [the defendant] thought he was cooperating with a regular FDA inspection, consent is not an issue because [he] was required to comply with a warrantless regulatory inspection . . . .")

87. *See*, *e.g.*, *Jamieson-McKames*, 651 F.2d at 539-40.

88. This is essentially FDA's policy. *See* IOM, *supra* note 17, at § 523.

89. FDA, given prioritization of limited resources, is also unlikely to bring forward a complaint for refusal to permit inspection solely for a refusal to permit photography, although this might be considered a partial refusal. Section 331(f) makes refusal to permit entry or inspection as authorized by section 374 of FDCA a prohibited act. 21 U.S.C. § 331 (f) (Supp. 2005). Refusal to permit inspection is discussed further below.

90. *See supra* Section II.A.

not be legitimate areas for Fourth Amendment protection against photography.[91] Absent Fourth Amendment protection, this issue will revolve around interpretation of FDCA.

IV. INTERPRETING THE FDA'S AUTHORITY TO TAKE PHOTOGRAPHS

A. Construction of the Statute

1. The Plain Language

The first rule of statutory construction is to look to the plain language of the statute.[92] FDCA Section 704 is silent as to the FDA's authority to take photographs during an inspection.[93] In addition, the legislative history of Section 704 is also silent on the issue of photographs.

However, not too much can be made from the statute's lack of specific mention of photography.[94] While FDCA does not specifically authorize photographs, it does not restrict FDA from taking photographs. FDCA provides FDA with broad authority and a few limitations.[95] Such limitations include (1) a general rule of reasonableness, (2) procedural requirements, and (3) some specific limitations regarding scope.[96] Inspections must be "at reasonable times and within reasonable limits and in a reasonable manner."[97] As to the procedural limits, before entering an establishment or inspecting, the FDA inspector[98] must present appropriate credentials and a written notice to the owner, operator, or agent in charge.[99]

---

91. *Id.*

92. Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984).

93. 21 U.S.C. § 374 (Supp. 2005) (mentioning the authority to enter, to inspect, sample, and access certain records).

94. With clients, it is important to avoid terminology that might lead them toward an inappropriate conclusion. In the author's experience, many will hear the statement, "FDCA does not *expressly* authorize the taking of photographs" as "FDCA does *not authorize* the taking of photographs."

95. *See supra* Section I.A.

96. *Id.*

97. 21 U.S.C. § 374(a)(1)(B) (Supp. 2005).

98. *See supra* note 21.

99. 21 U.S.C. § 374(a)(1) (Supp. 2005).

FDCA also imposes few specific limitations on the scope of the FDA's inspection authority. The most specific constraint is a limit on the FDA's access to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting requirements).[100]

When the reasonableness of an inspection has been challenged, courts largely make determinations based on whether FDA met the procedural requirements of Section 704.[101] Reasonableness will also be determined from the facts of each situation, such as the enforcement needs under the statute and whether an unnecessary burden is placed on a firm.[102] For example, inspection timing that would create a heavy overtime burden on a firm might raise the question of reasonableness.[103] However, if a manufacturing plant is operating on weekends or late at night, it would be reasonable for FDA to inspect during those times.[104]

Inspection reasonableness is also based on the enforcement needs under FDCA.[105] Photographs often can provide probative evidence of the conditions found during an inspection.[106] Therefore, photographs directly advance the purposes of the FDCA inspections. In light of the broad authority granted by FDCA and the few limitations, courts are likely to find that inspection photography

---

100. 21 U.S.C. § 374(a)(1) (Supp. 2005).

101. *See*, *e.g.*, *Gel Spice Co.*, 601 F. Supp. at 1228 (holding that photographing was not unreasonable where: "[t]he agents were in the warehouse pursuant to lawful authority and followed all procedural requirements mandated under 21 U.S.C. § 374").

102. *See*, *e.g.*, *Jamieson-McKames*, 651 F.2d at 537 (noting that the reasonableness of the warrantless search is dependent on the "specific enforcement needs and privacy guarantees of each statute").

103. "Burden" in this context includes neither the cost of compliance with the FDCA nor the financial repercussions of probative photographic evidence of non-compliance.

104. Durovic v. Palmer, 342 F.2d 634 (7th Cir. 1965), *cert. denied* 382 U.S. 820 (1965) (holding that a Saturday inspection was reasonable).

105. *See*, *e.g.*, *Jamieson-McKames*, 651 F.2d at 537 (noting that the reasonableness of the warrantless search is dependent on the "specific enforcement needs and privacy guarantees of each statute").

106. This analysis is akin to the balancing test of Rule 403 of the Federal Rules of Evidence. Rule 403 allows suppression of evidence if its probative value is substantially outweighed by the danger of unfair prejudice. FED. R. EVID. 403.

generally falls within the enforcement needs under FDCA, especially when photographs provide probative visual evidence of violations of the Act, such as insanitary conditions.

2. The Doctrine of Judicial Deference

The doctrine of judicial deference assumes that the interpretation given to a statute by the administrative agency charged with its execution is likely to be the most accurate.[107] This principal is also known as *Chevron* deference.[108]

Under the doctrine of *Chevron* deference, the court will apply a two-step analysis on the FDA's interpretation of terms in FDCA. The first step is to examine the language of the statute to determine if Congress directly spoke on that precise issue.[109] "[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute."[110] In the second step, if the FDA's interpretation is a "permissible" interpretation, even if not the best one, the court should defer to the FDA's interpretation.[111]

---

107. *Chevron*, 467 U.S. at 844:

> We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations 'has been consistently followed by this Court whenever decision as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations.' [citations omitted].

108. *See* Alaska Dep't of Env't Conservation v. E.P.A., 540 U.S. 461, 517 (2004) (5-4 decision) (Kennedy, J., dissenting) (referring to the application of *Chevron* at Chevron Deference).

109. *Chevron*, 467 U.S. at 842-43:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction of the statute, as would be necessary in the absence of an administrative interpretation.

110. *Id.*

111. *Id.* at 844.

Regarding inspection photography, nothing in the language of FDCA, nor in its legislative history, directly addresses the precise question at issue. Therefore, the courts would defer to the FDA's interpretation unless it is an impermissible construction of the statute.[112]

The two basic reasons for a court to find impermissible construction and overturn deference are that the statutory language is inconsistent with the agency's interpretation or the agency's reasoning is invalid.[113] As to the first reason, the FDA's interpretation does not clash with the plain language of FDCA.[114] Regarding the second reason to overturn, the FDA's reasoning for photographic authority appears valid on the surface.[115] The next three sections review the construction of FDCA to determine if there is any support for questioning the validity of the FDA's reasoning.

3. A Remedial Statute Designed to Protect the Public Health Should be Liberally Construed

In addition to the broad authority granted by the language of FDCA, the courts give liberal construction to the Act consistent with its overriding purpose to protect the public health.[116] In general, inspection photography advances the public health provisions of FDCA. Thus courts are likely to grant a liberal construction to the FDA's interpretation of FDCA giving the agency the authority to take photographs as part of an inspection.

---

112. *Id.*

113. United States v. 29 Cartons of . . . An Article of Food, Etc., 987 F.2d 33, 38 (1st Cir. 1993) ("When * * * a court is persuaded neither by 'the validity of [the agency's] reasoning,' nor by the interpretive fit between the agency's rendition, on the one hand, and the language and structure of the statute, on the other hand, a court should not defer." [citation omitted]).

114. *See supra* Section III.A.1.

115. *See supra* notes 16-22 and accompanying text.

116. United States v. Kordel, 164 F.2d 913, 917 (7th Cir. 1947), *cert. granted* 333 U.S. 872 (1948), *aff'd* 335 U.S. 345 (1948), *reh'g denied* 335 U.S. 900 (1948) and *reh'g denied* 336 U.S. 911 (1949).

> Courts for a long time have been committed to the doctrine of giving statutes intended to protect the public health a very liberal construction. As stated in Sutherland on Statutory Construction (Vol. III, sec. 7202), 'The public and social purposes served by such legislation greatly exceed the inconvenience and hardship imposed upon the individual, and therefore the former is given greater emphasis in the problems of interpretation. Therefore the courts are inclined to give health statutes a liberal interpretation despite the fact that such statutes are primarily penal in nature and frequently impose criminal penalties.'

4. Expressio Unius Est Exclusio Alterius

The FDCA's express limitation of the FDA's inspection authority in certain areas[117] may imply the exclusion of other similar limitations, such as photography. This rule of statutory interpretation is encapsulated in the maxim, "expressio unius est exclusio alterius," which literally means the expression of one thing is the exclusion of another.[118] The maxim does not apply to every statutory listing or grouping, but only when the listing justifies the inference that the items not mentioned were excluded by deliberate choice, not inadvertence.[119] In FDCA, the broad grant of inspection authority in Section 704 is restricted by a single sentence listing of areas and information excluded from the FDA's inspection authority.[120] This language tends to support the FDA's construction of the Act, because it supports the inference that Congress deliberately (rather than inadvertently) did not list photography in the exclusions from inspection authority.

---

117. 21 U.S.C. § 374(a)(1) (Supp. 2005) (referring to the limits upon the FDA's access to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting requirements)).

118. Bradley v. Board of Ed. Saranac Cmty. Schools, 565 N.W.2d 650, 656 (Mich. 1997).

119. Barnhart v. Peabody Coal Co., 537 U.S. 149, 168 (2003) ("As we have held repeatedly, the canon [expressio unius est exclusio alterius] does not apply to every statutory listing or grouping; it has force only when the items expressed are members of an 'associated group or series,' justifying the inference that items not mentioned were excluded by deliberate choice, not inadvertence."); *see also* Chevron U.S.A. Inc. v. Echazabal, 536 U.S. 73, 81 (2002) ("The canon depends on identifying a series of two or more terms or things that should be understood to go hand in hand, which is abridged in circumstances supporting a sensible inference that the term left out must have been meant to be excluded." (citing E. CRAWFORD, CONSTRUCTION OF STATUTES 337 (1940) (stating that expressio unius 'properly applies only when in the natural association of ideas in the mind of the reader that which is expressed is so set over by way of strong contrast to that which is omitted that the contrast enforces the affirmative inference' [citations omitted.])).

120. 21 U.S.C. § 374(a)(1) (Supp. 2005) (reading in pertinent part):

> No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data (other than data relating to new drugs, antibiotic drugs, and devices and subject to reporting and inspection under regulations lawfully issued pursuant to section 355(i) or (k) section 360i, or 360j(g) of this title, and data relating to other drugs or devices which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 355(j) of this title.

5. Doctrine of Legislative Acquiescence

Finally, the doctrine of legislative acquiescence looks to Congress's awareness of prior interpretations of its acts and finds that congressional failure to overturn an agency's interpretation indicates acquiescence to that interpretation.[121] The doctrine tends to support the FDA's interpretation on photography because the agency has been open about its interpretation FDCA regarding photography during inspections,[122] and Congress has had many years to restrict the FDA's authority to photograph. Therefore, the validity of the FDA's interpretation is supported to some extent by congressional failure to overturn it.[123]

In sum, the rules of statutory construction support the FDA's assertion of authority to take photographs during Section 704 inspections. The plain language of the FDCA and the rules of statutory construction also tend to support the validity of the FDA's reasoning for the authority. The next area where we can look for guidance is the case law.

---

121. United States v. Tuente Livestock, 888 F. Supp. 1416, 1424 (S.D. Ohio 1995) ("[T]he Court finds that the Congress'[s] awareness of the FDA's longstanding interpretation of the statute to permit action against those dealing in live animals, and its failure to prevent the FDA from acting upon that interpretation, does favor the agency's position in this case to some extent.").

122. IOM, *supra* note 17, at § 523.

123. *Tuente Livestock*, 888 F. Supp. at 1424.

B. Cases Cited by the FDA Inspectors

FDA cites two cases in its IOM[124] in support of its authority to take photographs: *Dow Chemical Co. v. United States*[125] and *United States v. Acri Wholesale Grocery Company*.[126] Although FDA offers these cases as proof of their authority to take photographs, others deny that these cases support the FDA's authority.[127]

The principal point made in this opposing reasoning is that neither *Dow Chemical* nor *Acri Wholesale* exactly addresses the FDA's authority to take photographs during inspections.[128] Specifically, *Dow Chemical* involved the Environmental Protection Agency (EPA), not FDA;[129] and *Acri Wholesale*, while it did address the FDA authority to take photographs, it did not decide whether a company might refuse the taking of photographs during an inspection without facing penalty.[130]

However, these contrary comments are oblique points drawing focus away from the answers provided by these two cases. These holdings answer whether an agency's authorizing statute must specifically mention photography as a tool, and also answer whether FDCA grants FDA the authority to take photographs during its inspections.

1. Dow Chemical Co. v. United States

In *Dow Chemical*, the Court upheld the taking of aerial photographs as a valid exercise of the EPA's inspectional powers under the Clean Air Act.[131] The Court also held that the EPA's

---

124. IOM, *supra* note 17, at § 523.01.

125. 476 U.S. 227 (1986).

126. 409 F. Supp. 529 (S.D. Iowa 1976).

127. As a food and drug law practitioner, I am often asked about the authority of these cases because if a firm refuses to allow FDA to take photographs, the FDA inspectors will refer to these two cases.

128. *See*, *e.g.*, Branding & Ellis, *Underdeveloped*, *supra* note 8, at 13 ("Neither *Dow Chemical* nor *Acri Wholesale Grocery Co*. specifically addresses [the] FDA's authority to take photographs during inspections and, more importantly, neither case addresses whether a company may refuse the taking of photographs during an inspection.").

129. *Dow Chemical*, 476 U.S. at 228.

130. *Acri Wholesale*, 409 F. Supp. 529.

131. *Dow Chemical*, 476 U.S. at 227-28.

photography was not a violation of Dow Chemical's Fourth Amendment privacy rights.[132] The Court said, "When Congress invests an agency such as EPA with enforcement and investigatory authority, it is not necessary to identify explicitly every technique that may be used in the course of executing the statutory mission."[133]

Food and drug attorneys who represent companies regulated by FDA are often critical of the FDA's reliance upon *Dow Chemical* to support its authority to take photographs during inspections. Their criticism stems from the fact that the case did not address the FDA authority, or photography during an establishment inspection.[134] Unfortunately, these statements are commonly misunderstood to mean that *Dow Chemical* is irrelevant to the FDA's authority.

A fair reading of *Dow Chemical* leads to the conclusion that it is not necessary for FDCA to mention photography for FDA to have authority to photograph during inspections. FDCA need not provide explicit reference to photography. After all, FDCA provides no explicit reference for inspectors to use pen and paper. For example, FDCA does not specifically authorize FDA to use ultraviolet lamps to detect rodent urine, but it would defy commonsense to prohibit FDA from using these lamps as an inspection tool based on the silence of FDCA.

Based on *Dow Chemical* reasoning, the FDA's authority to photograph is coextensive with the agency's authority to inspect. In addition, the documentation of the conditions and information found during an inspection is clearly part of congressional intent of FDCA.[135] Moreover, in creating the broad contours of the Section 704 inspection program, Congress would expect that FDA would formulate policy and rules to fill any gaps in the program.[136]

---

132. *Id.* at 228.

133. *Id.* at 228; *see also* IOM, *supra* note 17, at § 523.01.

134. This observation is based on the author's conversations with other practitioners. *See also* Branding & Ellis, *Underdeveloped*, *supra* note 8.

135. *See* 21 U.S.C. § 374(b) (Supp. 2005) (requiring inspection reports of conditions or practices observed).

136. *See Chevron*, 467 U.S. at 843 ("The power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." (citing Morton v. Ruiz, 415 U.S. 199, 231 (1974)).

2. United States v. Acri Wholesale Grocery Co.

The second case offered by FDA is *United States v. Acri Wholesale Grocery Co.*[137] In *Acri Wholesale*, the defendants first argued that the FDA's photographs were taken without the defendants' permission and were, therefore, inadmissible because photography was outside the scope of Section 704 inspections.[138] The court applied the flexible standard of reasonableness that defines the contours of an FDA Section 704 inspection and found that photographing warehouse conditions by FDA during inspections was not unreasonable. The photographs were taken pursuant to proper authority under Section 704 of FDCA.[139] In addition, because photographs would be cumulative of inspector testimony regarding the conditions on inspection, the photographs would not be unreasonable.[140]

The *Acri Wholesale* defendants also argued their rights under the Fourth Amendment were violated by the photography, which the defendants claimed exceeded the FDA's statutory authority.[141] The court held that, "[O]nce the validity of the inspection is established, the propriety of a photographic 'search' is coextensive with the validity of the inspection."[142]

The FDA's citation of *Acri Wholesale* to support their authority to take photographs[143] has been questioned because the defendants in that case were found to have fully consented to the inspections by FDA.[144] Therefore, the argument has been raised that the case does not support the FDA's

---

137. 409 F. Supp. 529 (S.D. Iowa 1976).

138. *Id.* at 532 ("In the first instance, defendants argue that the photographs were taken without their permission and are, therefore, inadmissible because the photographic activities were outside the scope of 21 U.S.C. § 374(a) (1970).").

139. *Id.* at 533 ("The Court believes, under the circumstances present in this case, the photographing of warehouse conditions by FDA agents was not unreasonable. The agents were in the warehouse pursuant to lawful authority and following all procedural requirements mandated under Section 374. . . . The Court therefore finds that the inspection was conducted pursuant to proper authority. . . .").

140. *Id.* ("Moreover, in this case the photographs introduced into evidence at trial were merely cumulative of the inspectors' testimony regarding the insanitary conditions in the warehouse.").

141. *Acri Wholesale*, 409 F. Supp. at 533.

142. *Id.*

143. IOM, *supra* note 17 at § 523.01.

144. *Acri Wholesale*, 409 F. Supp. at 533.

authority to take photographs absent consent, because the non-consent portions of the *Acri Wholesale* decision are dicta.[145]

However, the *Acri Wholesale* court found that "consent was an unnecessary basis" for the FDA's inspection authority.[146] Moreover, the *Acri Wholesale* court clearly issued what the court considered a ruling, not dicta, when the court held that the FDA's authority to take photographs was coextensive with the validity of their inspection.[147]

The *Acri Wholesale* decision is easily muddled, not because of the confusion over the FDA's right to take photographs without a warrant, but because the lack of the FDA's authority to force warrantless photography absent consent.[148] The lack of authority to force warrantless photography, however, does not equate with an establishment right to withhold consent.[149] While FDA would not be authorized to use force to take photographs pursuant to a Section 704 inspection,[150] an establishment's refusal to permit photographs would be a separate violation of FDCA.[151]

C. Additional Cases on the FDA's Inspectional Authority

Two additional cases address the FDA's inspectional authority to inspect or to take photographs during inspections:

1. United States v. Jamieson-McKames Pharmaceuticals, Inc.

United States v. Jamieson-McKames Pharmaceuticals, Inc.[152] focused on whether the drug manufacturing industry was properly within the *Colonnade-Biswell* exception to the search warrant

---

145. Branding & Ellis, *Underdeveloped*, *supra* note 8, at 14; *see also* Daniel F. O'Keefe, Jr., *Legal Issues in Food Establishment Inspections*, 33 FOOD DRUG COSM. L.J. 121, 130 (1978) (arguing that this *Acri* court finding was dicta because the defendants had consented).

146. *Acri Wholesale*, 409 F. Supp. at 533.

147. *Id.*

148. *See supra* Sections I and II.B.

149. *Id.*

150. *Id.*

151. *Id.* But whether a firm would ever be prosecuted for the violation is questionable. *See supra* Section I.D.

152. 651 F.2d 532 (8th Cir. 1981).

requirement.[153] The court found that the *Colonnade-Biswell* exception applied to inspections under FDCA; therefore, warrantless inspections under the Act did not offend the Fourth Amendment.[154]

Jamieson-McKames contended that its Fourth Amendment rights had been violated and moved for suppression of evidence taken by government agents.[155] Part of the disputed evidence was photographs of "the premises and contents" of the principal place of business of Jamieson-McKames.[156] The court treated the issue of suppression of the photographs no differently from other evidence obtained by the government agents.[157]

2. United States v. Gel Spice Co., Inc.

In *United States v. Gel Spice Co., Inc*.,[158] the defendant made several motions to suppress evidence, including one motion to suppress the photographs that FDA took during inspections.[159] The defendant argued that the photographs were unfairly prejudicial and that they were taken unlawfully.[160]

To the first argument—that the photographs were inflammatory and, therefore, unfairly prejudicial—the court held, "the standard for admissibility is whether the photos fairly and accurately depict the scene."[161] The defendant failed to come forward with evidence that the photographs contained distortions. The court held, "In addition, before the photographs can be admitted at trial, a proper foundation for their admission must be laid. Defendants will be amply protected by their opportunity to cross-examine the FDA investigator through whom the photographs are offered."[162]

---

153. *Id.* at 537.

154. *Id*.

155. *Id.* at 536. Both federal and state government agents entered the Jamieson-McKames premises. *Id*. at 535.

156. *Jamieson-McKames*, 651 F.2d at 535.

157. *Id.* at 540.

158. 601 F. Supp. 1214 (E.D.N.Y. 1985).

159. *Id*. at 1220.

160. *Id*.

161. *Id.*

162. *Id.*

The *Gel Spice* court additionally noted that while Rule 403 of the Federal Rules of Evidence allows suppression if the danger of unfair prejudice outweighs the probative value of the evidence, the defendant provided no basis for such a finding.[163] The court almost seemed to admonish the defendant, "of course, relevant evidence is by its very nature prejudicial. The test is whether it is *unfairly* prejudicial."[164]

The defendant's second argument—that the photographs were taken unlawfully—goes to the heart of the issue of the FDA's authority to take photographs in the course of administrative inspect-tions. Gel Spice argued that the photographs should be inadmissible because they were unreasonably taken during inspections.[165] The court applied Section 704's flexible standard of reasonableness that "define[s] the contours of an FDA inspection."[166] Under that standard, the court held that photographs of the warehouse conditions taken by the FDA inspectors during a Section 704 inspection were not unreasonable.[167] The court noted that the FDA inspectors had lawful authority under Section 704 to be at the premises and the procedural requirements of Section 704 were met.[168] The court concluded that with no evidence of the FDA's unlawfulness, and because of the reasonableness of the photography during the inspections, the photographs were not unlawfully obtained.[169]

The rule of *Gel Spice* is that FDA may take photographs during a lawfully conducted inspection when the FDA's procedural requirements for inspection are met and the photography is reasonably within the normal course of the inspection. In short, the *Gel Spice* decision supports photography as part of the FDA's broad inspectional authority based on a flexible standard of reasonableness.

---

163. *Gel Spice*, 601 F. Supp. at 1221.

164. *Id.* (emphasis in original).

165. *Id.* at 1228.

166. *Id*.

167. *Id.*

168. *Gel Spice*, 601 F. Supp. at 1228.

169. *Id.* at 1220.

V. CONCLUSION

The language of FDCA Section 704 provides FDA with broad inspectional authority based on a flexible standard of reasonableness. The statutory language and the case law support the conclusion that FDA may lawfully take photographs during a Section 704 inspection so long as the inspection is otherwise lawfully conducted, the FDA's procedural requirements for inspection are met, and the photography is within the normal course of the inspection.

In narrow circumstances, there may be a viable issue of whether the inspection itself (including the taking of the photographs) was reasonable. However, such determinations are likely to be ruled in the FDA's favor. The outcome of these decisions, of course, will be heavily dependant upon the particular facts and circumstances of the inspection and a firm's regulatory history.

Therefore, the common statement that the language of the FDCA Section 704 does not expressly authorize FDA to take photographs during inspections presents a misleading perspective. A fair summary of FDCA and the case law is that FDCA authorizes FDA to take photographs within the contours of a lawful inspection to advance the purposes of the Act.

Refusal to consent to photography as part of a lawful Section 704 inspection would be a partial refusal to permit the inspection, but it is arguable whether such a refusal would result in conviction for violation of Section 301(f).[170] Nevertheless, FDA is unlikely to pursue such a complaint—in part, because the issue remains unsettled—largely because of the pragmatic use of limited resources. Because this issue is unlikely to be settled by the courts and because of the damaging nature of photographic evidence, many firms are likely to continue to refuse to consent to photography, and FDA will be forced to seek administrative search warrants.

Considering the time and expense to the government of suspending an inspection, requesting a search warrant, and returning with federal marshals, efficiency calls for instructional language to be added to FDCA to make explicit the FDA's authority to take photographs during an inspection. Congress could accomplish this simply by placing language in Section 704 that states an inspection "includes, but is not limited to, photography." Alternatively, Congress could amend the Act and place the cost of refusing permission to photograph on the firm refusing such an inspection. This alternative could be accomplished by providing FDA with the authority to issue an administrative fine for refusal to permit photography. Such an administrative fine provision would also clarify the FDA's authority to take photographs, and refusals to permit photography would decline. An additional benefit of such amendments to FDCA would be to eliminate an area in the law that encourages conflict between the FDA and regulated firms.

---

170. 21 U.S.C. § 331(f) (Supp. 2005).

However, other than the controversy over the legality of refusing to consent to photography during an FDA inspection, the law on the FDA's authority to take photographs is clear. In essence, the FDA's authority to take photographs is coextensive with the agency's authority to enter and inspect.

As the saying goes, "A picture is worth 1,000 words,"—*not* that a picture is more than 1,000 words. Under the law, inspection photography is no more intrusive than other documentation. Where FDA has the authority to enter, inspect, and document the conditions in an establishment, the agency holds the authority to take photographs. In the 21st century, photographs are a reasonable way for FDA to document conditions in regulated establishments.